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APPELLANT:	Richard A. Gambale *et al.*
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APPEAL BRIEF

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TABLE OF CONTENTS

REAL PARTY IN INTEREST

The real party in interest is C.R. Bard, Inc. by reason of assignments from the inventors dated December 4, 1998, recorded on December 15, 1998 at Reel 9657, Frames 0366-0371.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 1-3, 5-13 and 33-45 are pending in the application. Claims 4 and 14-32 were canceled in a previous paper. Claims 1-3, 5-13 and 33-42 are allowed.

Claims 33-42 have been rejected and form the basis of this appeal.

STATUS OF AMENDMENTS

All amendments previously made have been entered. No new amendments have been made. Applicant's representative thanks the examiner for the telephonic interview of April 10, 2007 discussing the rejection of claims 33-42.

SUMMARY OF CLAIMED SUBJECT MATTER

Applicants' invention relates to methods for stimulating angiogenesis within a muscle by using a delivery system to access, penetrate and enclose within the muscle a body formed of a biocompatible material and dimensionally adapted for being enclosed within the muscle. The body both defines a lumen that is adapted to maintain an open cavity in the tissue sufficient to permit blood pooling and also has external projections configured to create cavities between the tissue and the body, so as to stimulate angiogenesis.

GROUNDS OF REJECTION TO BE REVIEWED UPON APPEAL

1. Whether each of claims 43-45 lack support and constitute new matter.

ARGUMENT

1. Claims 43-45 are Fully Supported by the Specification and Drawings as Originally Filed, and do not Constitute New Matter

The Federal Circuit has held that there is no requirement of literal textual recitation of claimed subject matter, only that the application reasonably convey that the inventor had possession at that time of the later claimed subject matter. The Manual of Patent Examining Procedure also espouses this view ("The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." MPEP § 2163.02).

a. Claim 43

Claim 43 was rejected as new matter on the ground that there is no support for the "proximal opening."

Claim 43 depends from allowed claim 1. Support for the proximal opening as recited in the claim can be found at page 21, lines 3-10, and FIGS. 6A and 6B. FIG. 6A shows the body in profile, with the opening to the central cavity 118 on the right. "The central cavity ends before the distal tip 120" of the body (page 21, lines 5-6 of specification). Applicants also note that the central cavity 118 in FIG. 6A is depicted by an arrow, and not in a cut-away view. The embodiment must necessarily have a proximal opening. Literal textual description is not required to satisfy the requirements of 35 U.S.C. § 112, (see, *e.g.*, *In re Wilder* (736 F.2d 1516, 222 U.S.P.Q. 369 (Fed. Cir. 1984)), *In re Gosteli* (872 F.2d 1008, 10 U.S.P.Q.2d 1614 (Fed. Cir. 1989))), and "drawings alone may provide a 'written description' of an invention as required by §112." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991).

Reversal of the rejection of claim 43 as new matter is therefore requested.

b. Claim 44

Claim 44 was rejected as new matter, on the ground that the lumen should be located in the bellows, not the spring. Page 10, lines 20-23 was cited.

Claim 44 depends from allowed claim 33, which recites that the body comprises a spring. Claim 44 further defines that the compound is within the lumen of the spring. That the spring itself defines a lumen is disclosed at page 10, lines 20-21 ("Alternatively, the drug releasing

compound can be contained within the lumen of a spring....”). Claim 44 as written is therefore fully supported by the specification as filed.

Reversal of the rejection of claim 43 as new matter is therefore requested.

c. Claim 45

Claim 45 was rejected as new matter, on the ground that nothing could be found in the specification at page 21, lines 3-10 concerning retention of a drug-releasing compound in the central tapered cavity.

Applicants note the claim 45, which recites a central tapered cavity, should depend from claim 43 (which also recites a central tapered cavity), rather than 44 (which recites a spring). The reference in claim 45 to a spring represents an obvious typographical error that would be immediately and unambiguously understood as such by one of ordinary skill in the art.

Support for the subject matter of claim 43 is set forth above. Claim 45 recites a central tapered cavity. The specification discloses that the drug-releasing compound can be in a reservoir constructed as an empty cavity within the device (page 10, lines 17-18 (“The reservoir can be constructed as an empty cavity within the device to be filled with a drug releasing compound.”)). The compound can also be affixed to a surface of the device (page 10, lines 1-3 (“As one embodiment, this apparatus can include an implant formed of a biocompatible material that has a drug releasing compound affixed to at least one of its surfaces.”)).

There is nothing at page 21, or anywhere else in the specification, that would lead one of ordinary skill to believe that there was any reason that the drug-releasing compound could not be placed within the cavity as recited in claims 43 and 45.

Reversal of the rejection of claim 45 as new matter is therefore requested.

CONCLUSION

For the foregoing reasons, the rejection of the claims was improper and should be reversed.

Respectfully submitted,

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APPENDIX A:

CLAIMS APPENDIX

1. (Previously presented) A method for stimulating angiogenesis within myocardial tissue, comprising:

employing a delivery system for accessing the myocardial tissue,

penetrating the myocardial tissue, and

operating the delivery system for enclosing within the myocardial tissue at least one body formed of a biocompatible material and dimensionally adapted for being enclosed within the myocardial tissue, wherein said body defines a lumen that is adapted to maintain an open cavity in the tissue sufficient to permit blood pooling in the lumen and the body comprises external projections configured to create cavities between the tissue and the body sufficient to permit blood pooling in the cavities, to thereby stimulate angiogenesis.

2. (Original) A method according to claim 1, wherein employing a delivery system includes employing a catheter delivery system.

3. (Previously presented) A method according to claim 1, wherein employing a delivery system for accessing the myocardial tissue includes

guiding a catheter delivery system through a patient's vascular system.

4. (Cancelled)

5. (Previously presented) A method according to claim 1, wherein penetrating the myocardial tissue includes driving a distal portion of the delivery system into the myocardial tissue.

6. (Previously presented) A method according to claim 1, wherein penetrating the myocardial tissue includes driving the at least one body into the myocardial tissue.

7. (Previously presented) A method according to claim 1, wherein operating the delivery system includes operating a delivery system that substantially seals the at least one body within the myocardial tissue.

8. (Previously presented) A method according to claim 1, wherein operating the delivery system for enclosing at least one body within the myocardial tissue includes implanting a plurality of bodies within the myocardial tissue.

9. (Previously presented) A method according to claim 1, wherein operating the delivery system for disposing at least one body within the myocardial tissue includes implanting at least one body adapted for promoting blood pooling within the myocardial tissue.

10. (Previously presented) A method according to claim 1, wherein operating the delivery system includes operating the delivery system for delivering into the myocardial tissue an agent for promoting angiogenesis.

11. (Previously presented) A method for stimulating angiogenesis within myocardial tissue, comprising:

accessing the myocardial tissue with a delivery system,

penetrating the myocardial tissue, and

releasing within the myocardial tissue at least one body formed of a biocompatible material and dimensionally adapted for being enclosed within the myocardial tissue, wherein said body defines a lumen that is adapted to maintain an open cavity in the tissue sufficient to permit blood pooling in the lumen and the body comprises external projections configured to create cavities between the tissue and the body sufficient to permit blood pooling in the cavities, to thereby stimulate angiogenesis, said biocompatible material being capable of inciting an inflammatory reaction with the tissue of the myocardial tissue.

12. (Previously presented) A method for promoting angiogenesis within myocardial tissue, comprising:

accessing the myocardial tissue with a delivery system,

penetrating the myocardial tissue,

releasing within the myocardial tissue at least one flexible body dimensionally adapted for implantation within the myocardial tissue, said body having been subjected to deforming stress prior to its release within the myocardial tissue and said body dynamically approximating the recovery of its native configuration after its implantation, and

withdrawing the delivery system from its proximity to the myocardial tissue.

13. (Previously presented) A method for promoting angiogenesis within myocardial tissue, comprising:

accessing the myocardial tissue with a delivery system,

penetrating the myocardial tissue,

releasing within the myocardial tissue a body formed of a heat responsive material, said body undergoing dimensional change upon exposure to intramuscular heat, and

withdrawing the delivery system from its proximity to the myocardial tissue.

14-32. (Cancelled)

33. (Previously presented) A method according to claim 1, wherein the body comprises a spring, further comprising at least one opening between the coils of the spring.

34. (Previously presented) A method according to claim 1 further comprising a drug releasing compound retained by a surface of the body.

35. (Previously presented) A method according to claim 34 wherein the drug releasing compound is contained within an internal reservoir of the body.

36. (Previously presented) A method according to claim 34 wherein the drug releasing compound is applied to a surface of the body by a coating.

37. (Previously presented) A method according to claim 34 wherein at least a portion of the body is formed from a drug releasing compound.

38. (Previously presented) A method according to claim 1 further comprising a radiation source carried by the body.

39. (Previously presented) A method according to claim 1, where the body is flexible and comprises a bellows for expanding and contracting responsive to myocardial tissue relaxation and contraction and wherein the external projections are defined by annular ripples.

40. (Previously presented) A method according to claim 1, where the body is flexible and comprises a plurality of tighter pitch spring sections connected by two open pitch spring elements, where the external projections are defined by the tighter pitch spring sections.

41. (Previously presented) A method according to claim 1, where the body is cone-shaped with a distal tip, and the external projections are a series of barbs on the external surface.

42. (Previously presented) A method according to claim 39, where the body further comprises an enclosed cavity and a port in the body open to the cavity and a drug releasing compound contained within the cavity, where during contraction of the bellows the compound diffuses through the port.

43. (Previously presented) A method according to claim 1, wherein the body is cone-shaped, further comprising a central tapered cavity with a proximal opening and a solid distal tip.

44. (Previously presented) A method according to claim 33, further comprising a drug releasing compound retained within the lumen of the spring.

45. (Previously presented) A method according to claim 44, further comprising a drug releasing compound retained within the central tapered cavity.

APPENDIX B:

TABLE OF CASES CITED